

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE (REV. 2-2005)		ATTORNEY'S DOCKET NUMBER <b>RLL-265US</b>
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/517,080</b>
INTERNATIONAL APPLICATION NO. <b>PCT/IB2003/002166</b>	INTERNATIONAL FILING DATE <b>06 June 2003</b>	PRIORITY DATE CLAIMED <b>07 June 2002</b>
TITLE OF INVENTION <b>SUSTAINED RELEASE ORAL DOSAGE FORMS OF GABAPENTIN</b>		
APPLICANT(S) FOR DO/EO/US <b>CHAWLA et al.</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> <li>11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409).</li> <li>12. <input type="checkbox"/> A copy of the International Search Report (PCT/ISA/210).</li> </ol> <p><b>Items 13 to 23 below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>13. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>15. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</li> <li>16. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</li> <li>17. <input type="checkbox"/> A substitute specification.</li> <li>18. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.</li> <li>20. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>21. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).</li> <li>22. <input checked="" type="checkbox"/> Express Mail Label No. <b>EV 674777181 US</b></li> <li>23. <input checked="" type="checkbox"/> Other items or information: <b>Certificate of Express Mailing</b> <b>Return postcard</b></li> </ol>		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/517,080		PCT/IB2003/002166		RLL-265US	
The following fees are submitted:				CALCULATIONS	PTO USE
24. <input type="checkbox"/> Basic national fee		\$300	\$	\$0.00	
25. <input type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4).		\$100	\$	\$0.00	
All other situations.		\$200			
26. <input type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority		\$100			
International Search Report prepared and provided to the Office		\$400	\$	\$0.00	
All other situations.		\$500			
TOTAL OF 24, 25 and 26 =			\$	\$0.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	0 /50 =	0	x	\$	\$0.00
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)).			\$		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x \$18.00	\$	\$0.00
Independent claims	- 3 =	0	x \$88.00	\$	\$0.00
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> +			\$	\$0.00	
TOTAL OF ABOVE CALCULATIONS =			\$	\$0.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			\$	\$0.00	
SUBTOTAL =			\$	\$0.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			\$	\$0.00	
TOTAL NATIONAL FEE =			\$	\$0.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +			\$	\$0.00	
TOTAL FEES ENCLOSED =			\$	\$0.00	
			Amount to be	\$	
			Amount to be	\$	
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0912</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
<p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p>Jayadeep R. Deshmukh, Esq. Reg. No. 34,507 Ranbaxy Inc. 600 College Road East, Suite 2100 Princeton, NJ 08540 Tel.: (609) 720-5608</p>					
			<p><u>William D. Hare</u> SIGNATURE</p> <p>William D. Hare NAME</p> <p>44,739 REGISTRATION NUMBER</p>		

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
**(Under 37 CFR 1.97(b) or 1.97(c))**

Docket No.  
**RLL-265US**

In Re Application Of: **CHAWLA et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
<b>10/517,080</b>	<b>12/6/2004</b>	<b>TBA</b>	<b>26815</b>	<b>2877</b>	<b>8568</b>

Title:  
**SUSTAINED RELEASE ORAL DOSAGE FORMS OF GABAPENTIN**

Address to:  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

**OR**

☐ the fee set forth in 37 CFR 1.17(p).

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
RLL-265US

In Re Application: **CHAWLA et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/517,080	12/6/2004	TBA	26815	2877	8568

Title:

**SUSTAINED RELEASE ORAL DOSAGE FORMS OF GABAPENTIN**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **50-0912** as described below.
- ☐ Charge the amount of \_\_\_\_\_
- ☐ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**Certificate of Transmission by Facsimile\***

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. \_\_\_\_\_)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Typed or Printed Name of Person Signing Certificate

**Certificate of Mailing by First Class Mail**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on \_\_\_\_\_

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
Signature of Person Mailing Correspondence

\_\_\_\_\_  
Typed or Printed Name of Person Mailing Certificate

**\*This certificate may only be used if paying by deposit account.**

  
\_\_\_\_\_  
Signature

Dated: May 5, 2005

**William D. Hare, Esq.**  
**Reg. No. 44,739**  
**Customer Number 26815**

cc:

<b>INFORMATION DISCLOSURE CITATION</b>	Docket No.: RLL-265US	Serial No.: 10/517,080
	Applicants: CHAWLA <i>et al.</i>	
	Filed: 12/6/2004	Group:

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	5,955,103	9/21/1999	Jao <i>et al.</i>	424	457	
	A2	6,054,482	4/25/2000	Augart <i>et al.</i>	514	561	
	A3	6,294,198	9/25/2001	Vilkov	424	465	
	A4	6,488,964	12/3/2002	Bruna <i>et al.</i>	424	490	
	A5	2002/091159	7/11/2002	Spireas	514	561	
	A6	2002/012679	1/31/2002	Bruna <i>et al.</i>	424	400	
	A7	2003/008004	1/9/2003	Vilkov	424	465	
	A8	2003/100611	5/29/2003	Berner <i>et al.</i>	514	561	

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES   NO
	B1	WO 00/59477	10/12/2000	PCT	A61K	9/20	
	B2	WO 00/76478	12/21/2000	PCT	A61K	9/16	
	B3	WO 01/51033	7/19/2001	PCT	A61K	9/20	
	B4	WO 03/02151	1/9/2003	PCT	A61K	47/24	
	B5	WO 03/35040	5/1/2003	PCT	A61K	9/20	
	B6	WO 03/103634	12/18/2003	PCT	A61K	9/22	
	B7	EP 0 284 849	8/4/1993	EPO	A61K	9/22	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: CHAWLA *et al.*

U.S. Application No.: 10/517,080  
 International Application No. PCT/IB2003/002166

International Filing Date: 6 June 2003

Title: SUSTAINED RELEASE ORAL DOSAGE FORMS OF  
 GABAPENTIN

**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that the following correspondence:

- Transmittal Letter to the DO/EO/US Concerning a Submission Under 371
- Transmittal of Information Disclosure Statement
- Information Disclosure Citation w/references
- Return Postcard

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on May 5, 2005

MICHELLE MORGAN  
 Name of Person Mailing Correspondence

Michelle Morgan  
 Signature

EV 674777181 US  
 "Express Mail" Mailing Label Number